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09/578,194	05/24/2000	Marcelo Domelas	0261	5443

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EXAMINER

SCHMIDT, MARY M

ARTICLE PAPER NUMBER

7035

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Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578.194

Applicant(s)

DORNELAS ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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DETAILED ACTION

1. The Official Action mailed 08 28 02 is vacated in favor of the Action below. Please note that an improper objection to the abstract of the specification was made in the previous Official Action necessitating the following new Action:
2. Applicant's election with traverse of Group II, claims 1-24, and election of species of the dzeta Ask gene of Group II and the plant species Arabidopsis in Paper No. 9, filed 06 11 02, is acknowledged. Applicant is reminded of MPEP 803.04 which states that "[n]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement." Applicant's traversal is on the ground(s) that the "specification clearly indicates that more than one of the Ask gene group II, is useable together. The Examiner has not shown that the alleged ASK gene Group II are actually independent inventions under this criteria." In view of MPEP 803.04, the different ASK genes of Group II are considered independent inventions based on their distinct and unique nucleic acid sequences. Although Group II genes have a high level of homology, sharing a significant nucleic acid sequence, the genes are not identical and the differences between them render them unique inventions. Similarly, the fact that the sense gene and the antisense gene, are two different sequences, these were also restricted. Applicant further traverses the rejection on the grounds that

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the must be a serious burden on the examiner for the search of the claimed invention. A serious burden was found to search and examine all the group II ASK sequences since the search of the claims is further drawn to issues of the development of the transformed plants after administration of either the sense or the antisense ASK gene sequence. Since administration of the sense sequence would not have the same effect as administration of the antisense sequence, and since each individual ASK gene type would have a different consideration for the administration and modification of the plant development, the search burden was rendered serious for a careful consideration of these different issues. Therefore, the inventions were found to be independent and a serious burden was found for search and consideration of all the group II ASK sequences as claimed.

The requirement is still deemed proper and is therefore made FINAL. Please note the claims are considered on the merits only as they are drawn to the elected inventions: ASK dzeta antisense in *Arabidopsis*.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Claim 20 contains a typographical error and does not properly depend on a claim having recombinant nucleic acid. (See the 35 U.S.C. 112, second para. rejection below) Since claim 20 is drawn to any plant comprising at least one cell, it reads on any naturally occurring plant in nature. Since products of nature can not be patented, claim 20 is rejected as containing non-statutory subject matter.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 contains a typographical error and lacks antecedent basis since it depends from itself. Correction is needed to amend the claim to make it properly dependant. Claim 21 is further rejected for its dependance on claim 20.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-19 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a methods, plants and seeds having transformed ASK dzeta antisense for generation of embryos that exhibit modified development.

The specification teaches on page 19 that the antisense used was a 300 bp fragment corresponding to the 5'-untranslated region and part of the N-terminal coding region of the ASK gene. The specification does not teach the design or use of other antisense to ASK dzeta with the function of modifying the embryo to exhibit an increased number of cotyledons.

One of skill in the art at the time the invention was made would not have recognized that Applicant was in possession of a representative number of species of antisense to ASK dzeta for use in the claimed methods and making the claimed plants and seeds. Dornelas et al. (Plant Mol. Biol. 39, 1999, cited by Applicant, on page 23 of specification) explain on page 140, figure 3, for instance, that the ASK genes share a core region of homology, and differ at the 5' and 3' ends only. One of skill in the art would have recognized that design of an antisense to the core region of ASK dzeta shared by other ASK sequences, would have led to antisense inhibition of other ASK genes as well, and would not have allowed for an expectation of success to make the specific plant modifications resulting from decreasing expression of ASK dzeta gene only. Since the specification as filed only provides written description support for the 300 base fragment at

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the 5' end of ASK dzeta, the claims are adequately described only for administration of this antisense fragment.

9. Claims 1-16, 19 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for production of a transgenic *Arabidopsis* via antisense to the ASK dzeta gene for the resulting modified development taught in the instant specification, development of an increased number of cotyledons, does not reasonably provide enablement for production of transgenic *Arabidopsis* via antisense to the ASK dzeta gene for any modified development as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1 (and dependent claims 4-16, 22 and 23) and claim 24 are drawn to methods and transgenic plants (*Arabidopsis*) having transformed ASK dzeta antisense for the production of a plant whose embryos exhibit "modified development." Claim 19 is included since it embraces a cell in a whole plant.

The specification as filed teaches on pages 18-22 that administration of the ASK dzeta antisense to *Arabidopsis* leads to increased number of cotyledons. The specification does not teach any other phenotypic modification of embryos for administration of antisense to ASK dzeta. The specification further teaches that the modifications of claim 2, abortion of the embryo

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was observed only with administration of antisense to the ASKetha gene, and not via administration of antisense to the elected species, ASK dzeta.

At the time the invention was made, the prior art taught the isolation of ASK group II genes, but did not teach a conclusive role of these genes in plant development. Dornelas et al. (Plant Mol. Biol. 1999) taught hybridization assays to determine the expression levels of various ASK genes in plants at different developmental stages, but did not teach gene knock-out experiments to determine gene functions. (They only taught on page 146 that "[s]creening of T-DNA insertion lines and transgenic *Arabidopsis* plants containing anti-sense constructs for the ASK genes is taking way in our lab to access additional information concerning the role of the ASK genes on plant development.") Dornelas et al. (The plant journal, 21 (5), 419-429, 2000 (date of availability was 4 5 00)) taught that AtSK11 and 12 function in perianth and gynoecium development, but did not address ASK dzeta development. Piao et al. (Plant physiology, 4 99, vol. 119, pp1527-1534) taught the role of an ASK iota complementary gene in NaCl stress signal pathway, but does not address ASK dzeta development. Tichtinsky et al. (cited by Applicant on page 23 of the specification) taught the role of ASK beta and theta in developing pollen, but did not specifically address the role of ASK dzeta in development. Dornelas et al. (Gene 1998, cited by Applicant on page 22 of the specification) taught a sequence structure and evolutionary comparison of the different ASK genes in *Arabidopsis*, but did not specifically teach the role of ASK dzeta in development.

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As such, the prior art did not provide any guidance as to what the expectation of success would be for administering antisense to ASK dzeta for the modified development of *Arabidopsis* embryos. Only Applicants' invention has shown the ability to increase the number of cotyledons in *Arabidopsis* embryos upon administration of antisense to ASK dzeta. However, these results do not correlate with an expectation of success that design and administration of any other antisense to ASK dzeta gene would result in other "modified development" results in the transgenic plants claimed. As argued above in the 35 U.S.C. 112, lack of written description rejection, it was mentioned that the high homology of the ASK gene family core region teaches that only certain regions of the ASK dzeta gene were available for the design of antisense specific to this ASK gene. As such, one of skill in the art would have recognized that the use of other antisense for administration to *Arabidopsis* would necessarily be designed to the same region as the 300 base pair fragment taught by Applicant, and that unless other variables were changed, such as where in the plant the antisense was administered, and at what developmental stage, Applicant would have had an expectation of the same results as taught in the instant specification upon down-regulation of the ASK dzeta gene. Furthermore, Applicant has not provided guidance as to how to transform *Arabidopsis* in any other way so that other modified development results may be achieved. In view of the teachings of the specification and of the prior art, and the lack of guidance for any other means for administration of antisense to ASK dzeta in *Arabidopsis* other than the methods exemplified in the specification, one of skill in the art would have had to practice an undue amount of experimentation to practice methods and

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make transgenic *Arabidopsis* plants and seeds with ASK dzeta antisense having embryo modifications other than having increased number of cotyledons.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dornelas et al. (Plant Mol. Biol. 39, 1999) and Dornelas et al. (The plant journal, 21 (5), 419-429, 2000, date of availability was April 5, 2000).

Dornelas et al. (1999) taught the 300 bp. antisense to ASK dzeta on page 138. While they did not teach specific insertion of this antisense in to a cloning vector and administration to *Arabidopsis*, they did teach on page 146 that "[s]creening of T-DNA insertion lines and transgenic *Arabidopsis* plants containing anti-sense constructs for the ASK genes is taking way in our lab to access additional information concerning the role of the ASK genes on plant development."

Dornelas et al. (2000) taught AtSK11 (ASK alpha) and AtSK 12 (ASK gamma) antisense constructs cloned in antisense orientation under the CaMV 35S promoter in a pEC2 plant

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transformation vector for expression in *Arabidopsis*. These are Group I ASK genes, and they did not specifically teach the cloning of ASK dzeta antisense.

One of ordinary skill in the art would have been motivated at the time the invention was made to design an antisense vector construct comprising at least one regulatory element operably linked in antisense orientation to a nucleic acid sequence encoding the ASK dzeta gene since (1) a specific and functional antisense to ASK dzeta was taught by Dornelas (1999) as well as the motivation to express said antisense in a whole plant, and (2) Dornelas et al. (2000) taught specific plant vectors and methods of making pEC2 plant transformation vectors for expression of ASK antisense constructs in *Arabidopsis*.

One of ordinary skill in the art would have been motivated to make an antisense construct comprising at least one regulatory element operably linked in antisense orientation to the ASK dzeta gene since Dornelas et al. (1999) specifically taught on pge 146 the use of such constructs for making transgenic *Arabidopsis* plants to gain "additional information concerning the role of th ASK genes on plant development."

One of ordinary skill in the art would have had an expectation of success to make the claimed ASK dzeta antisense constructs since absent evidence to the contrary, vector construction is a piece-meal practice, that was well-known at the time the invention was made, and further the pE2 vector taught by Dornelas et al. (2000) for expression of Group I ASK antisense in *Arabidopsis*, would have had an expectation of success for use in transformation of the antisense to ASK dzeta taught by Dornelas et al. (1999).

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12. Claims 1-16 and 22-24 are free of the prior art the closest prior art was design of antisense hybridization probe to ASK dzeta taught by Dornelas et al. (page 250 of Gene 212, 1998; page 138 of Plant molecular biology 39, 1999) but not for administration to whole Arabidopsis for making modified embryos.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt
August 28, 2002